

Food and Drug Administration 10903 New Hampshire Avenue Document Control Center – WO66-G609 Silver Spring, MD 20993-0002

May 12, 2015

ZIBO SANYING TRADE CO., LTD C/O Mr. Ray Wang Official Correspondent Beijing Believe Tech. Service Co., Ltd. 1-202, Build 3, Beijing New World, No. 5 Chaoyang Rd., Chaoyang District, Beijing, 100024 CHINA

Re: K150224

Trade/Device Name: Blue Vinyl Examination Gloves Powder Free

Regulation Number: 21 CFR 880.6250

Regulation Name: Vinyl Patient Examination Gloves

Regulatory Class: I Product Code: LYZ Dated: March 29, 2015 Received: April 1, 2015

Dear Mr. Wang:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the <u>Federal Register</u>.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Tejashri Purohit-Sheth, M.D.

Tejashri Purohit-Sheth, M.D. Clinical Deputy Director DAGRID/ODE/CDRH FOR

Erin I. Keith, M.S.
Division Director
Division of Anesthesiology, General Hospital,
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Radiological Health

Section II Indications for Use

DEPARTMENT OF HEALTH AND HUMAN SERVICES Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120 Expiration Date: January 31, 2017 See PRA Statement below.

Indications for Use		See PRA Statement below.
510(k) Number <i>(if known)</i> K150224	•	
Device Name BLUE VINYL EXAMINATION GLOVES POWDER FREE		
ndications for Use (Describe)		
The BLUE VINYL EXAMINATION GLOVES POWDER FREE is a disposable device intended for medical purposes that is worn on the examiner's hands or finger to prevent contamination between patient and examiner.		
Гуре of Use (Select one or both, as applicable)		
Prescription Use (Part 21 CFR 801 Subpart D)		er Use (21 CFR 801 Subpart C)

CONTINUE ON A SEPARATE PAGE IF NEEDED.

This section applies only to requirements of the Paperwork Reduction Act of 1995.

DO NOT SEND YOUR COMPLETED FORM TO THE PRA STAFF EMAIL ADDRESS BELOW.

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Department of Health and Human Services Food and Drug Administration Office of Chief Information Officer Paperwork Reduction Act (PRA) Staff PRAStaff@fda.hhs.gov

"An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB number."

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